

REMARKS

Remarks

Claim 86 is pending in the present application. Examiner is thanked for his withdrawal of prior pending objection and 103(a) rejection. Claim 86 is rejected under 112, first paragraph, written description.

Rejection Under 35 USC § 112, first paragraph, Written Description

Claim 86 is rejected under 35 USC § 112, first paragraph for containing subject matter which was not described in the specification in such a way to reasonably convey to one skilled in the relevant art that the inventor(s), at the time of the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection.

Specifically, the Examiner states that “to provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing characteristics of the genus.” Pending Action, page 4. Applicants note that the present invention is directed towards methods of using an “engineered” fusion protein that contains “identical epitopes.” Examiner additionally states that the factors to be considered in determining if “sufficient distinguishing characteristics” have been provided include “functional characteristics.” *Ibid.* The Examiner defines the invention as “a method of detecting specific antibodies in experimental or clinical samples, wherein said method comprises providing an ubiquitin fusion protein comprised of one or more epitope-containing segments comprising two or more identical epitopes.” As the Examiner acknowledges in the pending Action, Applicants have defined the genus functionally by defining the term epitope. Pending Action, page 3. Nevertheless, the Examiner continues to state that the “claim does not require that the epitopes of the instant invention have any particular biological activity, or any particular structure.” Pending Action, page 3. In fact, the epitopes of the present invention do have a particular biological activity. They are recognizable by antibodies, B cells and T cells. That is, they are antigenic. Antigenicity is their functional characteristic, by definition. Epitopes need not have any innate biological activity other than to be recognized by an antibody, B cell or T cell (*i.e.*, be antigenic). This is known by those of skill in the relevant art. Thus, the “epitopes” of the present invention are defined by the “functional characteristic” of antigenicity thereby satisfying the written description requirement.

The term "identical" is also known by those of skill in the relevant art as meaning "the same" ("being the same" Merriam-Webster Dictionary). Thus, the phrase "identical epitopes" would be fully understandable by one of skill in the relevant art as meaning epitopes that are the same. Furthermore, one of skill in the relevant art would understand how to construct fusion proteins. Thus, one of skill in the relevant art would reasonably convey that the specification contained subject matter which was described in the specification in such a way to reasonably convey to that the inventor(s), at the time of the application was filed, had possession of the claimed invention.

Applicants note that the Examiner made a very similar, if not fundamentally identical, rejection in the Action mailed from the Patent Office on October 18, 2005 (see, page 5, first paragraph of that Action). As the Examiner admitted in that Action in regard to the present invention, "such assays can be performed with any protein or polypeptide antigen..." Action dated October 18, 2005, page 3. The terms "protein" and "polypeptide antigen" are admitted by the Examiner to be synonymous with the term "epitope." "[A]ntigenic epitopes can be interpreted as any antigenic polypeptide or protein." Action dated October 18, 2005, page 5. The Examiner also admitted in that Action that "antigenicity" is a functional characteristic. "[T]he functional characteristic of antigenicity." *Ibid*, page 5, second paragraph. The Examiner is respectfully reminded that the same claim limitation of "identical epitopes" was pending at that time. That written description rejection was withdrawn in response to Applicant's arguments (mailed April 17, 2006). Applicants respectfully request the withdrawal of the presently pending rejection and allowance of the pending claim.

Summary

In light of the above amendment, consideration of the subject patent application is respectfully requested. Any deficiency or overpayment should be charged or credited to Deposit Account No. 50-4514.

Respectfully submitted,



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